

09/866,030

4

**REMARKS**

Claims 6, 10-15 and 21-26 are pending in the application. Claims 24, 25, and 26 are independent claims.

Claims 6, 10, 15, and 21-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite.

The proper standard for determining definiteness under 35 U.S.C. 112, second paragraph, is whether a claim reasonably apprizes those of skill in the art of its scope. See *In re Warmerdam*, 33 F.3d 1354, 1361, 31 USPQ2d 1754, 1759 (Fed. Cir. 1994); *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.* 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991).

1. The Examiner takes issue with the use of the phrase "a support having first and second ends". Specifically, the rejection proffers that it is unclear to define an end on a support that has six sides. The rejection is traversed. A review of Claim 24 as well as the specification as filed, demonstrates that Applicants clearly defined the "first and second ends" in a manner that is consistent with its ordinary meaning and is well understood by ordinary practitioners in the field of biosensors.

The Examiner's attention is directed to the specification, which defines an embodiment of the substrate as having "first and second ends" (page 1 lines 14-15). Still further, the specification describes the substrate of Figures 2 and 3 including a "first surface 24 . . . a second surface 26 . . . opposite first and second ends 28, 30 and opposite edges 32, 34 extending between the first and second ends 28, 30" (page 3 lines 12-15). As such, it is recognized by the specification that the support has a plurality of "sides", two of which are first and second ends. As such, it is submitted that the specification and claims use the term "first and second ends" in a manner consistent with their ordinary meaning.

In general, the absence of a limitation in a claim that is described in the specification does not make a claim indefinite. *In re Wakefield*, 422 F. 2d 897, 164 USPQ 636 (C.C.P.A. 1970). *Wakefield* instructs that the definiteness of claim language is

09/866,030

5

measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification. Such an indefiniteness rejection can be properly attacked for failure to establish a prima facie case of indefiniteness. *Id.* Accordingly, while recognized by the text of the specification, it is submitted that there is no requirement under 35 U.S.C. 112, second paragraph, to define an additional 4 "sides" in Claim 24. As such, the use of the phrase "first and second ends" is sufficient to meet the requirements under Section 112, second paragraph.

2. The rejection proffers that the phrase "electrode array" as recited is unclear to define two pairs of electrodes and call it an array. That proffer is traversed.

A review of Claim 24 as well as the specification as filed, demonstrates that Applicants clearly defined the "electrode array" in a manner that is consistent with its ordinary meaning and is well understood by ordinary practitioners in the field of biosensors.

The Examiner's attention is directed to the specification and Figure 2, which defines the substrate as supporting two spaced-apart electrode arrays (page 2 lines 20-21). Further, "electrodes 14, 16, 18 cooperate with one another to define first and second electrode arrays 76, 78 and leads 80 that extend away from the first and second arrays 76, 78" (page 4 lines 19-21). As such, Applicants have described "electrode arrays" both in the text of the application as well as the drawings. It is submitted that the use of the phrase "electrode arrays" in the text of the specification as well as by reference in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

However, even if the Examiner is unfamiliar with the use of the term "array" to define the described and illustrated arrays, a claim should not be rejected as indefinite if the patent applicant merely uses new terminology that was formulated to describe an aspect of the invention. It is a fundamental principle under Section 112, second paragraph, the inventors may act as their own lexicographers. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F. 2d 881, 221 USPQ 1025, 1031 (Fed. Cir. 1984); *Fromson v.*

09/866,030

6

*Advance Offset Plate, Inc.*, 720 F. 2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

Thus, a claim may not be rejected solely because of the type of language used by an applicant to define the subject matter for which patent protection is sought. The specification and drawings are replete with description of electrode arrays (page 1 lines 16-17 and 32-33, page 2 lines 20-21; page 4 lines 19-27; page 5 lines 3-5; page 6 lines 9-12, 17-19, 25-27; page 10 lines 8-11 and 19-22; and Figures 1B, 2, and 4 ). Applicants have described "electrode arrays" both in the text of the application as well as the drawings.

Accordingly, the phrase "electrode arrays" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

3. The rejection proffers that the phrase "a spacer having individual members" is unclear. The Examiner recommends claiming 2 spacers that cooperate with each other to define a capillary channel that extends between the two spacers. The rejection and recommendation is traversed.

A review of Claim 24 as well as the specification as filed, demonstrates that Applicants clearly defined the phrase "a spacer having individual members" in a manner that is consistent with its ordinary meaning and is well understood by ordinary practitioners in the field of biosensors.

As best illustrated in Figure 2, Applicants have defined the spacer substrate 20 as having a first member 40 and second and third members 42, 44 spaced-apart from the first member 40 (page 4 lines 28-30). Additionally, the specification recites that when the spacer substrate 20 is coupled to the support 12, the electrode arrays 76, 78 are positioned to lie between the first member 40 and the second and third members 42, 44 (Page 5 lines 3-5). It is submitted that the use of the phrase "a spacer having individual members" in the text of the specification as well in the drawings is

09/866,030

7

consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

However, even if the Examiner is unfamiliar with the use of the phrase "individual members", a claim should not be rejected as indefinite if the patent applicant merely uses new terminology that was formulated to describe an aspect of the invention. It is a fundamental principle under Section 112, second paragraph, the inventors may act as their own lexicographers. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F. 2d 881, 221 USPQ 1025, 1031 (Fed. Cir. 1984); *Fromson v. Advance Offset Plate, Inc.*, 720 F. 2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

Thus, a claim may not be rejected solely because of the type of language used by an applicant to define the subject matter for which patent protection is sought.

Description of the spacer in the specification and drawings is discussed above.

As such, the phrase "individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

4. The phrase "a cover cooperating with the support to define a capillary channel extending between the individual members" is rejected. The rejection proffers that "the cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this." That proffer is traversed.

In general, the absence of a limitation in a claim that is described in the specification does not make a claim indefinite. *In re Wakefield*, 422 F. 2d 897, 164 USPQ 636 (C.C.P.A. 1970). *Wakefield* instructs that the definiteness of claim language is measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification. Such an indefiniteness rejection can be properly attacked for failure to establish a prima facie case of indefiniteness. *Id.*

09/866,030.

8

Here, it is sufficiently definite to recite in claim 24, a channel defined by a cover and a support. Additional details regarding the sides of the channel are not required. It is of note, however, that claim 24 recites that the channel extends between the individual members of the spacer. Thus, the communication between each object is shown.

As such, the phrase "a cover cooperating with support to define a capillary channel extending between the individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

5. The phrase "the channel having opposite ends" is found to be unclear, as it is indefinite to claim a channel having opposite ends. The proffer is traversed.

Claim 24 is amended, however, as matter of preference in describing the claimed invention. The amendment to claim 24 is not meant as a reflection of changes deemed necessary for patentability purposes. Specifically, claim 24 is amended to recite "the channel having opposite outlets". Support for the amendment is found in the specification and drawings and particularly at page 6 lines 2-4.

It is submitted that the phrase "the channel having opposite outlets" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

6. The phrase "a concave inlet extending from the first end of the support and being positioned between opposite ends of the channel" is found to be unclear due to the phrase "first end". That proffer is traversed.

The Examiner's attention is directed above to point number 1. It is submitted that the phrase "first end" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

09/866,030

9

The rejection goes further to question whether the inlet is the channel and to require Applicants to "define the positioning and orientation of the inlet with respect to the channel" This is traversed.

Claim 24 recites that the channel has "a concave inlet". It is submitted that the use of the term "inlet" with respect to a channel is in accordance with its ordinary meaning that is well understood by ordinary practitioners in the field of biosensors. Further, claim 24 recites that this inlet extends from "the first end of the support". This provides sufficient description regarding the inlet's positioning and orientation on the biosensor. Still further, claim 24 recites that the inlet is positioned between the opposing outlets of the channel. As such, its positioning and orientation with respect to the channel as a whole is defined.

As such, it is submitted that the phrase "a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

7. The phrase "each electrode array being positioned in the channel adjacent to one of the opposing ends" is found to be unclear. Here again, the Examiner takes issue with the term "arrays". The rejection is traversed.

The Examiner's attention is directed above to point number 2 regarding the discussion of definiteness for the phrase "electrode arrays". In light of the above discussion, the phrase "electrode arrays" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

The rejection further questions the phrases "opposing ends" and makes the comment "Adjacent to what?". As discussed above, claim 24 is amended to recite opposing outlets. Still further, it is submitted that it is sufficiently clear from the text of the claim, the specification, and drawings that each electrode array is positioned in the

09/866,030

10

channel adjacent to one of the opposing outlets of the channel). As such, its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

In light of the above discussion, it is submitted that Claim 24 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Regarding claim 25:

I. The Examiner takes issue with the use of the phrase "a support having first edge". Specifically, the rejection proffers that it is unclear to define an edge on a support that has six sides. The proffer is traversed.

A review of Claim 25 as well as the specification as filed, demonstrates that Applicants were not acting as their own lexicographer, but rather clearly defined the "first edge" in a manner that is consistent with its ordinary meaning. Attention is directed to Claim 25, which recites "a support having a first edge". It is submitted that the phrase "first edge" as used above is in accordance with its ordinary meaning that is well understood by ordinary practitioners in the field of biosensors.

In that regard, attention is directed to the specification, which defines an embodiment of the substrate as having "first surface 24 . . . a second surface 26 . . . opposite first and second ends 28, 30 and opposite edges 32, 34 extending between the first and second ends 28, 30" (page 3 lines 12-15 and Figures 2 and 4). As such, it is recognized by the specification that the illustrated support has a plurality of "sides", one of which is a first edge. As such, it is submitted that the specification and claims use the term "first edge" in a manner consistent with its ordinary meaning.

In general, the absence of a limitation in a claim that is described in the specification does not make a claim indefinite. *In re Wakefield*, 422 F. 2d 897, 164 USPQ 636

09/866,030

11

(C.C.P.A. 1970). *Wakefield* instructs that the definiteness of claim language is measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification. Such an indefiniteness rejection can be properly attacked for failure to establish a prima facie case of indefiniteness. *Id.*

Accordingly, while recognized by the text of the specification, it is submitted that there is no requirement to define additional “sides” of a support in Claim 25. As such, is the use of the phrase “first edge” is sufficient to meet the requirements under Section 112, second paragraph.

2. The phrase “first and second electrode sets positioned on the support spaced apart from one another” from Claim 25 is rejected as being unclear and indefinite. The rejection is traversed. The Examiner requests details on where on the support and what orientation are the electrodes are related to each other.

Again, in general, the absence of a limitation in a claim that is described in the specification does not make a claim indefinite. *In re Wakefield*, 422 F. 2d 897, 164 USPQ 636 (C.C.P.A. 1970). *Wakefield* instructs that the definiteness of claim language is measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification. Such an indefiniteness rejection can be properly attacked for failure to establish a prima facie case of indefiniteness. *Id.*

Accordingly, it is submitted that it is sufficiently definite to recite that the sets are positioned on the support. Exact details set forth in the specification as to their location and orientation are simply not required by 35 U.S.C. 112, second paragraph. As such, the use of the phrase “first and second electrode sets positioned on the support spaced apart from one another” is sufficient to meet the requirements under Section 112, second paragraph.

3. The rejection proffers that the phrase “a spacer having individual members” is unclear. The proffer is traversed. The Examiner suggests claiming 2 spacers that



09/866,030

12

cooperate with each other to define a capillary channel that extends between the two spacers.

A review of Claim 25 as well as the specification as filed, demonstrates that Applicants clearly defined the phrase "a spacer having individual members" in a manner that is consistent with its ordinary meaning and is well understood by ordinary practitioners in the field of biosensors.

As best illustrated in Figure 2, and as discussed above with reference to claim 24, Applicants have defined the spacer substrate 20 in the specification as having a first member 40 and second and third members 42, 44 spaced-apart from the first member 40 (page 4 lines 28-30). Additionally, the specification recites that when the spacer substrate 20 is coupled to the support 12, the electrode arrays 76, 78 are positioned to lie between the first member 40 and the second and third members 42, 44 (Page 5 lines 3-5). It is submitted that the use of the phrase "a spacer having individual members" in the text of the specification as well in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

However, even if the Examiner is unfamiliar with the use of the phrase "individual members", a claim should not be rejected as indefinite if the patent applicant merely uses new terminology that was formulated to describe an aspect of the invention. It is a fundamental principle under Section 112, second paragraph, the inventors may act as their own lexicographers. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F. 2d 881, 221 USPQ 1025, 1031 (Fed. Cir. 1984); *Fromson v. Advance Offset Plate, Inc.*, 720 F. 2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

Thus, a claim may not be rejected solely because of the type of language used by an applicant to define the subject matter for which patent protection is sought.

Description of the spacer in the specification and drawings is discussed above.

As such, the phrase "individual members" is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the

09/866,030

13

specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

4. The phrase “a cover having a second edge and extending across the first and second electrode sets” is rejected. The rejection is traversed in light of the amendment.

Specifically, the rejection proffers that it is unclear and indefinite to claim an edge on a cover. A review of Claim 25 as well as the specification as filed, demonstrates that Applicants were not acting as their own lexicographer, but rather clearly defined the “second edge” in a manner that is consistent with its ordinary meaning. Attention is directed to Claim 25, which recites “a cover having a second edge”. It is submitted that the phrase “second edge” as used above is in accordance with its ordinary meaning that is well understood by ordinary practitioners in the field of biosensors.

In that regard, attention is directed to the specification, which defines an embodiment of the cover substrate as having “an inner surface 58 . . . and an outer surface 60 . . . opposite first and second ends 62, 64 and edges 66, 68 extending between the first and second ends 62, 64” (page 5 lines 21-23). As such, it is recognized by the specification in one embodiment of the cover has a plurality of “sides”, one of which is a second edge. As such, it is submitted that the specification and claims use the term “second edge” in a manner consistent with its ordinary meaning.

In general, the absence of a limitation in a claim that is described in the specification does not make a claim indefinite. *In re Wakefield*, 422 F. 2d 897, 164 USPQ 636 (C.C.P.A. 1970). *Wakefield* instructs that the definiteness of claim language is measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification. Such an indefiniteness rejection can be properly attacked for failure to establish a prima facie case of indefiniteness. *Id.* Accordingly, while recognized by the text of the specification, it is submitted that there is no requirement to define additional “sides” in Claim 25. As such, the use of the phrase “second edge” is sufficient to meet the requirements under Section 112, second paragraph.

09/866.030

14

Further, the rejection proffers that it is likely that the edge is not extended across the first and second electrode. In that regard, the examiner is referred to the use of the conjunction "and" in the claim. Claim 25 recites not that the second edge extends . . . , but rather that the cover having a second edge *and* extending across". However, in an effort to further clarify the claim, Claim 25 is amended to recite "a cover having a second edge, the cover extending across the first and second electrode sets".

As such, the phrase "a cover having a second edge, the cover extending across the first and second electrode sets" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

5. The phrase "the cover cooperating with support to define a generally linear capillary channel extending between the individual members" is rejected. The rejection is traversed.

Specifically, the phrase "generally linear channel" is found to be unclear and indefinite". A review of Claim 25 as well as the specification as filed, demonstrates that Applicants clearly defined the phrase "a generally linear capillary channel" in a manner that is consistent with its ordinary meaning and well understood by ordinary practitioners in the field of biosensors.

Applicants have described a generally linear capillary channel in the specification (page 1 line 28; page 6 lines 1-2). Additionally, the drawings, Figure 1A, for example, illustrates this generally linear design. It is submitted that the use of the phrase "generally linear channel" in the text of the specification as well in the drawings is consistent with its ordinary meaning and would be well understood by ordinary practitioners in the field of biosensors.

However, even if the Examiner is unfamiliar with the use of the phrase "generally linear channel", a claim should not be rejected as indefinite if the patent applicant merely uses new terminology that was formulated to describe an aspect of the invention. It is a fundamental principle under Section 112, second paragraph, the

09/866,030

15

inventors may act as their own lexicographers. *Lear Siegler, Inc. v. Aeroquip Corp.*, 733 F. 2d 881, 221 USPQ 1025, 1031 (Fed. Cir. 1984); *Fromson v. Advance Offset Plate, Inc.*, 720 F. 2d 1565, 1569, 219 USPQ 1137, 1140 (Fed. Cir. 1983).

Thus, a claim may not be rejected solely because of the type of language used by an applicant to define the subject matter for which patent protection is sought.

Description of the generally linear channel in the specification and drawings is discussed above.

As such, the phrase "generally linear channel" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

In addition, the rejection proffers that "the cover and the support only define 2 sides of the channel. The other two sides come from the spacers. The applicant claim needs to state this". That proffer is respectfully traversed.

Again, in general, the absence of a limitation in a claim that is described in the specification does not make a claim indefinite. *In re Wakefield*, 422 F. 2d 897, 164 USPQ 636 (C.C.P.A. 1970). *Wakefield* instructs that the definiteness of claim language is measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification. Such an indefiniteness rejection can be properly attacked for failure to establish a prima facie case of indefiniteness. *Id.*

Here, it is sufficiently definite to recite in claim 25, a cover cooperating with the support to define a capillary channel. Additional details regarding the sides of the channel are not required. It is of note, however, that claim 25 recites that the channel extends between the three members of the spacer, thus demonstrating communication between each object in a clear and concise manner.

As such, the phrase "the cover cooperating with the support to define a generally linear capillary channel extending between the individual members" is fully supported

09/866,030

16

by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

6. The phrase “the channel having opposing first and second ends and an inlet aligned with the first edge of the support and the second edge of the cover” is rejected. The Examiner questions “How does a channel have opposing first and second ends if it is not a totally closed channel, sounds more like a chamber”. The proffer is traversed.

Claim 25 is amended as matter of preference in describing the claimed invention. The amendment to claim 25 is not intended to be a reflection of changes deemed necessary for patentability purposes. Specifically, claim 25 is amended to recite “the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel”. Support for the amendment is found in the specification and drawings and particularly at page 6 lines 1-6 and Figure 1B.

It is submitted that the phrase “the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel” is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

The rejection further proffers that “First edge of the support and the second edge of the cover is unclear and indefinite, where are the spacers in this orientation?” The rejection is traversed. As discussed above in points 1 and 4, the phrase “first edge of the support and the second edge of the cover” are fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

09/866,030

17

Regarding the location of the spacer, claim 25 recites that the cover cooperates with the support to define a generally linear capillary channel extending between the individual members. As such, it is submitted that the location of the spacer is sufficiently defined relative to the cover and substrate. The apparent request by the Examiner to incorporate additional details from the specification into Claim 25 is traversed.

In general, the absence of a limitation in a claim that is described in the specification does not make a claim indefinite. *In re Wakefield*, 422 F. 2d 897, 164 USPQ 636 (C.C.P.A. 1970). *Wakefield* instructs that the definiteness of claim language is measured solely on the basis of the elements recited in the claim and not in view of additional unrecited features described in the specification. Such an indefiniteness rejection can be properly attacked for failure to establish a prima facie case of indefiniteness. *Id.*

Here, it is sufficiently definite to recite in claim 25, a generally linear capillary channel extending between the individual members. Additional details regarding the sides of the channel are not required by 35 U.S.C. 112, second paragraph. As such, the meaning of the phrase "the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover" is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

7. The phrase "between the ends of the channel" is rejected. The rejection is traversed.

As discussed above in point 6, Claim 25 is amended to recite "the channel having opposing first and second outlets" Support for the amendment is found in the specification and drawings and particularly at page 6 lines 1-6 and Figure 1B.

It is submitted that the phrase "between the outlets of the channel" is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by

09/866,030

18

ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

8. The phrase “and between the first and second electrode sets” is rejected as being unclear and indefinite. The rejection is traversed.

Specifically, the rejection proffers that “The biosensor needs to show communication between each object in a clear and concise manner in which one of ordinary skill in the art would be able to have a clear understanding of the invention. It is submitted that claim 25 satisfies such a communication.

In that regard, the Examiner's attention is directed to the language of claim 25. Claim 25 recites, “first and second electrode sets positioned on the support spaced-apart from one another”, satisfying communication between the electrode sets and the substrate. Next Claim 25 recites a cover “extending across the first and second electrode sets”, satisfying communication between the electrode sets and the cover. Still further, Claim 25 recites an inlet to the channel positioned “between the first and second electrode sets”, satisfying communication between the electrode sets and the channel. As discussed above, the channel itself is defined by the cover and support and extends between members of the spacer. Accordingly, it is submitted that the electrode sets are defined by claim 25 with reference to each of the elements – substrate, cover, and spacer – of the claim.

As such, the phrase “between the first and second electrode sets” is fully supported by the specification and drawings and its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

In light of the above discussion, it is submitted that Claim 25 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

09/866,030

19

Claim 26 is rejected as having the same problems as mentioned in Claim 24 and Claim 25. The rejection is traversed for the reasons stated above with reference to Claims 24-25.

It is of note that Claim 26 is amended as matter of preference in describing the claimed invention. The amendment to claim 26 is not intended to be a reflection of changes deemed necessary for patentability purposes. Specifically, claim 26 is amended to recite a channel having "spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members, each electrode array being positioned in the channel adjacent to one of the opposite outlets". Support for the amendment is found in the specification and drawings and particularly at page 6 lines 1-6 and Figure 1B.

In light of the above discussion with reference to Claims 24 and 25, it is submitted that Claim 26 is fully supported by the specification and drawings and as such its meaning is sufficiently clear from both its description in the specification as well as its ordinary meaning understood by ordinary practitioners in the field of biosensors for purposes under Section 112, second paragraph.

Accordingly, Claims 24-26 are sufficiently definite for purposes under Section 112, second paragraph. Claim 6 depends from claim 24, claims 10-15 depend from claim 25, and claims 21-23 depend from claim 26. Reconsideration of the rejection, leading to its withdrawal and allowance of the claims is respectfully requested.

Claims 6, 10-15, and 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nankai et al. (USPN 5,120,420).

Nankai et al. discloses a biosensor that includes a base plate having an electrode system. By integrating with a cover, a space including the reaction layer is formed and an introducing port for introducing a sample solution into the space and a discharge port for discharging a gas in the space by inflow of the sample solution. See, Column 3 lines 5-15.



09/866,030

20

It is submitted that the resulting modification proffered by the rejection fails to show or suggest a device as recited in claims 24, 25, and 26. The rejection proffers that "it would have been obvious . . . to change the shape of an object. The spacer of Nankai performs the same function of the spacer in the instant application, it provides 2 sides of a channel in which a fluid flows there through, the other sides of the channel are provided by the cover and the substrate". The proffer is traversed in light of the following remarks.

It is true that Nankai et al. describes a spacer and that the claims of the present invention recite a spacer. It is also true that spacers are known to function by providing sides of a channel. It is not the case, however, that spacers are the same and that their configuration changes are obvious, as proffered by the rejection. It is the configuration of the spacer in conjunction with the substrate, electrodes, and the cover, which provides a unique and unobvious biosensor configuration as it relates to claims 24-26.

A key difference between the biosensors of Nankai et al. and Claims 24-26 relates to the flow pattern of the liquid sample within the biosensors. In that regard, the Examiner's attention is directed to each of the Figures of Nankai et al., where it is illustrated that a resulting liquid flow pattern would be essentially forward moving. There is certainly no opposing dual-directional flow taught or suggested by Nankai et al. In fact, Nankai et al. teaches away from such an arrangement.

In that regard, the Examiner's attention is directed to Nankai et al. at column 5 lines 19-36:

When the introducing port at the tip of the glucose sensor constructed as described above is brought into contact with a glucose standard solution (200 mg/dl), which is a sample solution, the sample solution is introduced into the inside through the introducing port 10. In this case, the air in the space 8 is rapidly discharged through the discharge port 11 and at the same time, the space is filled up with the sample solution up to near the discharge port. As such, the sample solution rapidly spreads onto the electrode surface to fill up the space so that any remaining air bubbles are not noted.

09/866,030

21

This is believed to be because the sample solution would flow into *one direction* by providing the introducing port and the discharge port and due to the hydrophilic high molecular substance layer previously formed on the electrodes, wetting on the electrode surface would be improved so that the gas is smoothly exchanged with the liquid. (emphasis added)

As such, Nankai et al. teaches dual-directional flow as being worse than one-directional flow achieved by its disclosed biosensor configuration.

It is important to note that each of the biosensors of claims 24-26 is configured for and operate using opposing dual-directional flow of a liquid sample applied to its respective inlet.

For example, Claim 24 recites "a capillary channel extending between the individual members, the channel having opposing outlets and a concave inlet extending from the first end of the support and being positioned between the opposing outlets of the channel". With an inlet positioned between opposing outlets, opposing dual directional flow of a liquid introduced into the inlet is achieved.

Claim 25 recites "a generally linear capillary channel extending between the individual members, the channel having opposing first and second outlets and an inlet aligned with the first edge of the support and the second edge of the cover, between the outlets of the channel, and between the first and second electrode sets". Again, with an inlet positioned between opposing outlets, opposing dual directional flow of a liquid introduced into the inlet is achieved.

Claim 26 recites a channel "extending between the three members and having an inlet positioned between the second and third members adjacent to the first end of the support and spaced-apart first and second opposite outlets, the first opposite outlet being positioned between the first and second members and the second opposite outlet being positioned between the first and third members". Again, opposing dual directional flow of a liquid introduced into the inlet is achieved.

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22

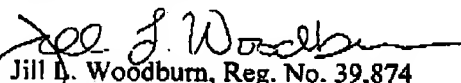
As such, Nankai et al. teach away from the biosensors recited by Claims 24-26 and cannot be said to render the pending claims obvious.

It is respectfully contended that the differences between the claimed invention and the cited art are such that Applicant's invention as a whole would not have been obvious to one of ordinary skill in the art at the time the invention was made. It is respectfully contended that the claimed invention meets the test of patentability under 35 U.S.C. 103(a). Entry of the amendments, reconsideration of the rejections of the claims, and withdrawal of the rejections leading to allowance of the claims is respectfully requested.

The claims as submitted herein are believed to be in condition for allowance, and allowance of the application is respectfully requested. In addition, it is requested that if necessary that this paper be considered a request for extension of time sufficient to effect a timely response and that that all fees due be charged to Deposit Account Number 02-2958 with reference to (WP 19301 US).

Respectfully submitted,

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